OCT - 6 2003

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

K032407

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
(714) 516-7488 - Facsimile
Colleen Boswell - Contact Person

Date Summary Prepared: July 2003

Device Name:

- Trade Name – Optiband LC
- Common Name – Orthodontic Band Cement
- Classification Name – Bracket Adhesive Resin and Tooth Conditioner. per 21 CFR § 872.3750

Devices for Which Substantial Equivalence is Claimed:

- 3M Unitek Dental Products Division, *Transbond Plus*

Device Description:

The device is a resin-based fluoride releasing band cement. It is a single paste so messy powder and liquid mixing is eliminated as well as inconsistent mixing of catalyst/activator type cements. *Optiband LC* achieves high strength following light cure allowing active archwires to be placed immediately. *Optiband LC* has higher tensile and compressive strength than glass ionomers or zinc phosphates and does not have an unpleasant taste or odor. It is specially formulated to have high adhesion to enamel and metal surfaces to reduce the chances of wash-out and loose bands. *Optiband LC* is offered in two shades, chromatic formula and blue formula.

Intended Use of the Device:

The intended use of *Optiband LC* is as a light-cured orthodontic band cement that is designed for the attachment of orthodontic appliances to teeth.

Substantial Equivalence:

Optiband LC is substantially equivalent to other legally marketed devices in the United States. *Optiband LC* functions in a manner similar to and is intended for the same use as *Transbond Plus* that is currently marketed by 3M Unitek Dental Products Division.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2003

Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K032407
Trade/Device Name: Optiband LC
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Codes: DYH
Dated: July 31, 2003
Received: August 04, 2003

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I - Indications for Use

Ver/ 3 - 4/24/96

Applicant: Ormco Corporation

510(k) Number (if known): K032407

Device Name: Optiband LC

Indications For Use:

Optiband LC Band Cement is a light-cured orthodontic bonding cement that is intended to be used for the attachment of orthodontic appliances to teeth.

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K032407

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)
(Optional Format 1-2-96)